

How to Interact with the Natural and Non-prescription Health Products Directorate Electronically

Guidance Document



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1. INTRODUCTION

This document is intended to provide a summary of information on how to interact electronically with the Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada. A key objective of the Natural Health Products Online Solution (NHPOLS) is to provide an end-to-end process for the electronic exchange of protected information between the NNHPD and applicants.

By taking advantage of the electronic tools available through the NHPOLS, applicants will experience an efficient, secure, and cost-effective way of submitting applications and dealing with the NNHPD electronically. The benefits are:

- Quick and cost-effective means of communication
- Reduced frequency of application errors
- Receipt confirmations and tracking
- All correspondence sent in electronic (.pdf) format, resulting in less paper

1.1 SYSTEM REQUIREMENTS

To use the electronic forms associated with the NHPOLS most effectively, be sure that your workstation meets the System Requirements.

2. EPOST CONNECT™

epost Connect™ is the digital delivery platform with bank-grade encryption that facilitates the sending and receiving of confidential messages and documents with one or multiple recipients. epost Connect™ also enables seamless, secure collaboration with one or many customers, clients, colleagues, partners and suppliers through one common platform.

The NNHPD is migrating towards a full electronic application process. As part of the initiative, epost Connect™ will become the primary method of electronic communication between the NNHPD and applicants, regarding applications. This includes information request notices, licences, and decision documents.

The NNHPD directs these correspondences from epost Connect™ to the contact email listed on the application form. In order to communicate electronically in this fashion, applicants need to register an account with epost. Applicants do not need to register as a Trading Partner to correspond in this fashion.

If you are a Trading Partner, you can submit new applications (e.g. product, site, clinical trials, master files, etc.) electronically via a specific conversation in epost Connect™, without signatures on the document, as becoming a Trading Partner associates your signature with your email address. See section 3 for information on Trading partners and how to enroll.

Applicants will not be required to purchase a licence for the epost Connect™ system. All 'conversations' will be initiated by the NNHPD via the epost Connect™ system for the

purposes of correspondence with the NNHPD. Applicants will need only to respond as outlined in the instructions below.

2.1 ROLES

2.1.1 NNHPD

- Initiate correspondence conversations with application contacts
- Send correspondence through designated (submission specific) conversations
- Save and store all correspondence and documents sent via conversations in their systems. Delete conversations 15 days after a decision has been issued on an application (licensed, refused or withdrawn). Only these conversations will be removed.

2.1.2 APPLICANT

- Register for an epost Connect™ account with Canada Post
- Respond to inquiries sent by the NNHPD regarding pending applications
- Save and store all correspondence and documents sent by the NNHPD on their systems. Conversations in epost Connect™ will be deleted by the NNHPD 15 days after a decision has been issued on an application (licensed, refused or withdrawn). Only these conversations will be removed.

For guidance through all epost Connect™ process, you can view the instructional video at epost.ca/connect.

2.2 EPOST CONNECT™ ENROLMENT

Applicants must obtain an account with epost Connect™ to access the communications from the NNHPD electronically. Registering an account with epost Connect™ is free and takes less than 5 minutes.

2.3 CORRESPONDING

You will receive a notification via email informing you that you have received an invitation to join a conversation from a collaborator. The email address of the collaborator will be identified in the email notification text. To access the message click on the link “Access the Message”. You will then land on the epost Connect™ log-in page.

This is how the email notification looks:



Figure 1: Example of an epost Connect™ message.

All electronic correspondence must be sent through the epost Connect™ interface by replying/posting within the message and nothing should be sent directly to NNHPD email accounts. Email sent to these addresses outside of the epost Connect™ system will not be accepted or responded to.

Some of the benefits of receiving communications from the NNHPD via epost Connect™ include:

- 'No fee' service
- Transmit electronic files in any format, up to 1GB in size (each)
- No paper involved
- Multiple contacts can view and respond to the same message
- Correspondence requests and responses are tracked as a conversation, meaning the history of applications can be readily viewed in one convenient location

- Conversation tracking allowing all participants to check receipt of message, and whether the message was opened by another participant
- Security and confidentiality is maintained

3. TRADING PARTNER

A user must enrol and become a registered Trading Partner in order to communicate with the NNHPD electronically through epost Connect™.

The NNHPD deals electronically with three types of Trading Partner:

1. The applicant company
2. A third-party consultant, submitting on behalf of the applicant company
3. Both applicant company and third-party consultant

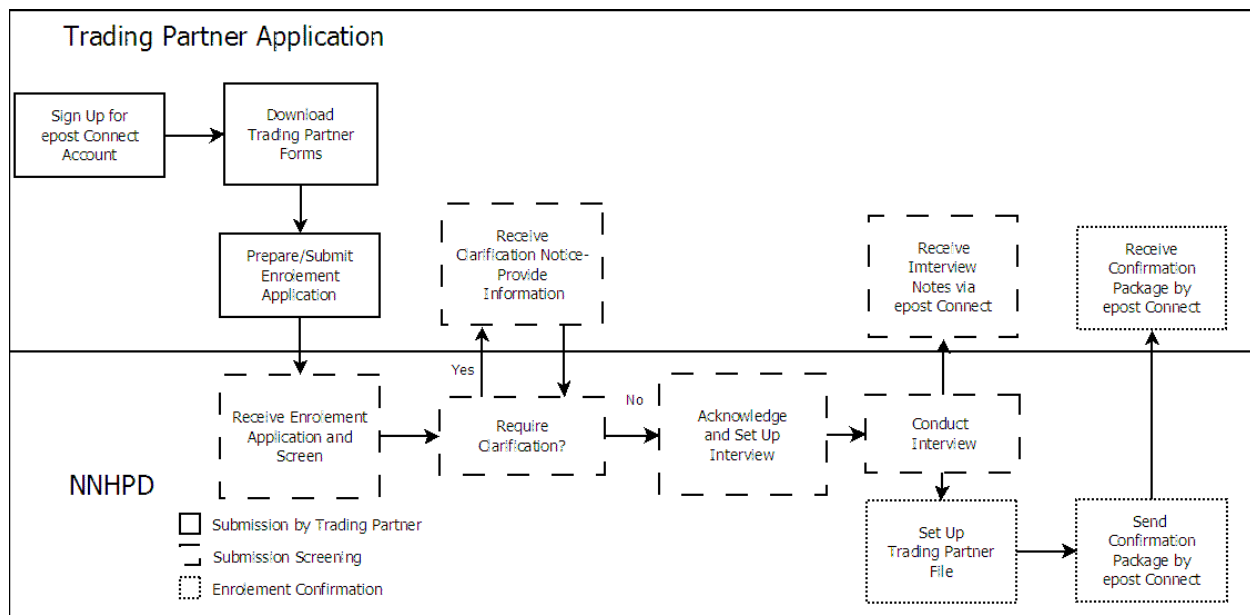


Figure 2: Flowchart of the Trading Partner Enrolment Process

3.1 ROLES

Before beginning the Trading Partner enrolment process, it is recommended that a company defines users for the following roles.

3.1.1 TRADING PARTNER (THE APPLICANT COMPANY)

A Trading Partner may be:

- An entity that has the status of a person in law (proof required)
- A person or an entity created by law to conduct commercial business

- A corporation, division, law firm, consultant firm or another business or company who has a legally registered business name
- A self-employed or natural person who has a registered business, such as a consultant, naturopath, shop owner, etc.
- A partnership between two companies who have legally registered business names and a partnership agreement that recognizes their partnership

A Trading Partner may have:

- Only one Primary User
- One or more Delegated Users

3.1.2 PRIMARY USER

- A person who signs the Trading Partner agreement on behalf of the Trading Partner (applicant company) (requires proof of authority to sign, refer to Section 3.2.3)

The Primary User:

- Is held legally accountable by the NNHPD for all electronic activity submitted by all users on behalf of the Trading Partner
- Can delegate or revoke authority to others (Delegated Users) to transact electronically with the NNHPD on behalf of the Trading Partner, but is still held accountable for this activity
- Is responsible for keeping all the Trading Partner information up to date (i.e. Delegated Users, contact information, company name, etc.)

3.1.3 DELEGATED USER

- A person who has been designated by the Primary User to transact electronically with the NNHPD on behalf of the Trading Partner (e.g. send documents)

The Delegated User:

- Can submit changes to their own information (e.g. update to email address, phone number, etc.)
- Can be from the Primary User's company or a Third-Party Consultant, in which case the third-party company must also enrol as a Trading Partner

Notes:

- There can be any number of Delegated Users for a Trading Partner
- Delegation remains in effect until revoked by the Primary User

3.1.4 DELEGATED USER WITH PRIMARY USER ACCESS

A Delegated User with Primary User Access:

- Does not have the authority to change the relationship between the Primary User and the Trading Partner

- May perform the functions of the Primary User if delegated by the Primary User
- May delegate or revoke authority to others (Delegated Users) to transact electronically with the NNHPD on behalf of the Trading Partner
- When applicable, is responsible for keeping all the Trading Partner information up to date (i.e. Delegated Users, contact information, Company Name, etc.)
- Must be from the Primary User's company

Each user indicated above must have an active epost Connect™ email address to uniquely identify them. The NNHPD Trading Partner enrolment process establishes the epost Connect™ address of each individual as the electronic equivalent of a personal signature; therefore, each address must be exclusive to the individual. The Trading Partner can sign up for one epost Connect™ account (address) with Canada Post and then create a unique sub-account for each user. Please refer to the epost Connect™ website for more information and how to create sub-accounts.

3.2 TRADING PARTNER ENROLMENT

The enrolment process begins by downloading the necessary forms. A completed enrolment package will include the following information:

- 2 completed and signed copies of the Trading Partner Agreement (Section 3.2.1)
- 1 completed and signed copy of the Trading Partner Profile form (Section 3.2.2)
- 1 Proof of Signing Authority (Section 3.2.3)
- 1 Proof of legal name (Section 3.2.3)

3.2.1 TRADING PARTNER AGREEMENT

The Trading Partner Agreement sets out the terms and conditions available to the Trading Partner for the purpose of communicating electronically with the NNHPD.

A company doing business under a different name from the true name of the owner must indicate both its legal (registered) name and its trade name on the Trading Partner Agreement. If a partnership exists, it should also set out the names of the partners.

NOTE: The person who signs the Trading Partner agreement must be the Primary User. This should be the same individual identified as having signing authority in the Proof of Signing Authority document. (Section 3.2.3)

3.2.2 TRADING PARTNER PROFILE FORM

The Trading Partner Profile form identifies all Trading Partner information, such as users, roles, contact information and shared secrets. The NNHPD uses this form to initialize and update Trading Partner accounts.

The Trading Partner Profile form is completed using Adobe Reader software (Section 1.1 - System Requirements). It must be downloaded and completed on the user's workstation.

NOTE: The form may open in the browser window; however, the form will not function properly if completed in the browser window. The form must be downloaded and/or saved and opened from the user's workstation prior to completion.

The form can be completed in either English or French by selecting the appropriate button at the top of the form. To enrol as a new Trading Partner, select the option for 'New Trading Partner Profile'. All required fields are marked by an asterisk (*); the form cannot be finalized or submitted until all required fields are completed.

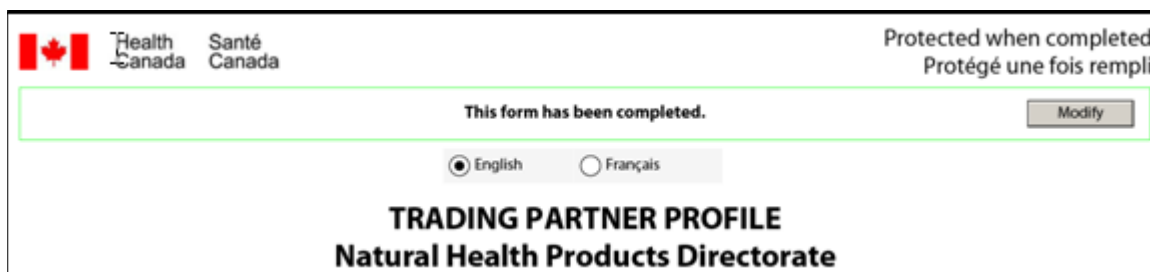
Part 1 of the form is used to identify the Trading Partner in Section A and Primary User in Section B. Section C defines the Shared Secrets; these four questions are used to authenticate the identity of the Primary User during the enrolment process. The answers to these pre-determined questions should be brief, unique to the individual, and easy to remember.

NOTE: The Primary User should answer these questions and take note of the answers as they will be requested during the enrolment process.

Part 2 of the form is for the Primary User to identify any Delegated Users who will be authorized to transact on behalf of the Trading Partner. To add more than one Delegated User, select the 'Add a Delegated User' button. A delegated user does not need to be identified during enrolment, and can be added at a later date. For more information, refer to Section 3.3 - Maintaining Trading Partner Status.

A Delegated User can be assigned designated authority privileges that would allow them to act as the Primary User to add and remove other Delegated Users on the Trading Partner Profile, as well as modify the contact information of the Trading Partner. The Trading Partner Profile form currently does not allow for this to be indicated and thus the Primary User must submit a letter along with the Trading Partner Profile form indicating which, if any, Delegated Users would have such authority.

Once completed, the form must be finalized by pressing the 'Finalize' button. The form will not finalize until all mandatory fields have been completed. Upon finalization, a green box will appear at the top and bottom of the form with the message: 'This form has been completed'. Only forms that display this message will be accepted by the NNHPD.



The screenshot shows the top portion of a web form. At the top left is the Health Canada logo with the text 'Health Canada / Santé Canada'. At the top right, it says 'Protected when completed / Protégé une fois rempli'. A green-bordered box contains the text 'This form has been completed.' and a 'Modify' button. Below this are two radio buttons: 'English' (which is selected) and 'Français'. At the bottom of the form, the text 'TRADING PARTNER PROFILE' and 'Natural Health Products Directorate' is displayed.

Figure 3: Screenshot of part of the finalized Trading Partner Profile form.

Once finalized, the **Attestation** section must be signed by the Primary User before submitting to the NNHPD.

It is strongly recommended to save and store your completed Trading Partner Profile form. Should you wish to modify it in the future (contact changes, trading partner info changes), you will be able to work directly off of this form by selecting 'Modify' instead of starting a new application. See Section 3.3 for more information on making changes to an existing Trading Partner profile.

3.2.3 PROOF OF LEGAL AUTHORITY

As part of the Trading Partner application, proof of the Primary User's legal capacity to sign the Trading Partner Agreement on behalf of the Trading Partner must be provided. There are two types of supporting documents required:

1. Proof of the legal name of the Trading Partner; and
2. Authorization that the named Primary User has the legal authority to sign on behalf of the Trading Partner.

The supporting documentation will depend on the individual Trading Partner circumstances. For example:

1. **Proof of the legal name of the Trading Partner:**

For a corporation, any one of:

- Certificate of Incorporation (showing incorporated name, business address and officers/senior official) provided by the Ministry of Consumer and Commercial Relations; or
- Letters patent or any other official incorporation document.

For a natural person who has a registered business name, any one of:

- Business Registration; or
- Goods and Services Tax notice from the Canada Revenue Agency.

For a partnership:

- Partnership agreement (showing partnership name, business address and names of partners).

2. **Authorization that the named Primary User has the legal authority to sign on behalf of the Trading Partner:**

All Trading Partner enrollees will need a letter stating that the named Primary User has the legal authority to sign on behalf of the Trading Partner; letter must be written on corporation letterhead signed by a senior official within a company. Proof of a senior official's authority to designate a Primary User may be required if their name is not stated in the documentation used for Proof of legal name.

NOTE: Not sure what supporting documents to provide? Contact the [NNHPD](#) by email.

3.2.4 SUBMITTING ENROLMENT APPLICATION AND PROCESS

Submitting enrolment application:

The completed enrolment package must include:

- Two signed, original copies of the Trading Partner Agreement;
- One completed and signed original Trading Partner Profile Form; and
- Proof of legal capacity to sign on behalf of the Trading Partner, including one proof of signing authority and one proof of legal name.

Two Trading Partner Agreements need to be completed in full and sent to the NNHPD so that the NNHPD can keep one on record and provide one to the applicant for record purposes.

Enrolment requests cannot be processed without appropriate and complete supporting documentation.

The enrolment package must be submitted to the NNHPD by regular mail or courier (fax and regular email submission will not be accepted), as the enrolment application requires that signed originals be provided.

Packages must be delivered to:

Health Canada
Health Products and Food Branch
Natural and Non-prescription Health Products Directorate
NHP Online Trading Partner Enrolment
250 Lanark Avenue
A.L. 2003B
Ottawa, Ontario K1A 0K9
Canada
(Couriers: K1Z 1G4)

The Primary or Delegated User may check the status of the enrolment request by contacting the NNHPD by email.

Enrolment Application Process at the NNHPD

Review of the enrolment application begins once the complete package is received by the NNHPD. The Primary User may be contacted if the NNHPD has any questions or requires any clarifications about the enrolment package contents. The NNHPD will schedule a telephone interview by contacting the Primary User at the epost Connect™ email address that was indicated on the Trading Partner Profile form. The telephone interview with the Primary User is to confirm the contents of the Trading Partner Profile that was included as part of the enrolment submission (i.e. the answers to the shared secrets), and takes minimal time (approximately 5 minutes). The NNHPD will then approve the enrolment based on the results of the interview and contents of the application.

Confirmation of Enrolment

When the enrolment application is approved, the NNHPD will activate the Trading Partner Natural Health Products Online System account and set up the Primary User and any Delegated Users for the Trading Partner.

Upon successful enrolment, the Trading Partner receives the following:

- A confirmation message sent to the Primary User by epost Connect™ secure email; and
- A signed copy of the Trading Partner Agreement sent by regular mail.

NOTE: It is important that during the Trading Partner enrolment process the Primary User checks their epost Connect™ email for any important correspondence.

The NNHPD will create a conversation with its registered Trading Partners (TPs) regarding new applications. This conversation will act as an inbox for new applications for each TP. When a TP has a new submission to send to the NNHPD, access your epost Connect™ account and 'post'/submit the related submission package via this conversation initiated by the NNHPD.

3.3 MAINTAINING TRADING PARTNER STATUS

It is important to keep the Trading Partner Profile up to date as correspondence can be sent at any time from the NNHPD. The Trading Partner Profile form is used to maintain trading partner information, such as:

- Trading Partner company information (name, address, etc.);
- Contact information for Primary or Delegated Users;
- Adding or revoking Delegated Users;
- Shared Secrets.

NOTE: Since all conversations must be initiated by the NNHPD, all TPs will be able to send in updates and manage their Trading Partner Profile (TPP) (contact information changes, delegated user changes, etc.) through the initial TP conversation.

NOTE: The NNHPD must be notified of any changes to the Primary User. Failure to do so may result in a temporary suspension of the Trading Partner Agreement until further notice.

To make changes to an existing Trading Partner, select the 'Modify Existing Trading Partner Profile' at the top of the Trading Partner Profile form.

TRADING PARTNER PROFILE Natural Health Products Directorate

New Trading Partner Profile

This form must be completed, printed and signed by the Primary User. It is to be sent along with the rest of the NHP On-line enrolment request documents to the Natural Health Products Directorate (NHPD).

Please note: Part 1 MUST be completed and the Attestation MUST be signed.

Modify Existing Trading Partner Profile

When modifying Trading Partner information, the entire block **A. - Trading Partner** must be completed. Supporting documents may be required - see Trading Partner Profile guidance for details.

When modifying Primary User information, the Trading Partner Legal Name in block A and the entire block **B. - Primary User** must be completed. Shared Secrets answers may also be modified if desired.

When managing Delegated Users, the Trading Partner Legal Name in block A, the Primary User Surname and Given Name, and the Primary User PosteCS Address in block B must be provided.

Figure 4: Screenshot of form to modify an existing Trading Partner

Each section of the Trading Partner Profile form has a modify button, which can be selected to indicate that changes are being made. For Delegated Users, there are three options:

1. Add – to be used when adding new Delegated Users
2. Modify – to be used when revising information for existing Delegated Users
3. Revoke – to be used when a Delegated User is no longer active

Revised Trading Partner Profile forms must be finalized to ensure that all mandatory fields are complete before sending to the NNHPD. Modified forms do not require a signature and the NNHPD will accept modified forms by email through epost Connect™.

All modified Trading Partner Profile forms can be sent by posting through the epost Connect™ NNHPD-initiated TP conversation.

4. SUBMITTING ELECTRONIC APPLICATIONS

The Natural Health Products Online Solution's suite of tools provides a completely electronic process for product licence applications. Using the electronic Product Licence Application form (ePLA) allows the applicant to take advantage of the many benefits offered. When combined with the electronic Submission Builder (eSB), the applicant benefits from the enforced requirements. Using these tools together helps to minimize the chance of refusals and deficiency requests/follow-up, as well as the time taken for processing the applications.

Some general requirements when using the electronic tools:

- ePLA must be finalized; unfinalized ePLAs will be returned to the applicant
- the eSB package (.hcs format) must be validated; unvalidated packages will be returned to the applicant

For more information on the ePLA, please refer to the [Natural Health Product Licence Application Form User Manual](#).

For more information on the eSB, please refer to the [NHP Online eSubmission Builder](#).

4.1 SUBMITTING THROUGH EPOST CONNECT™

The most efficient way to submit an ePLA is through epost Connect™ email. It is important to note that:

- The NNHPD only accepts packages from enrolled Trading Partners through epost Connect™ when the conversation has been initiated by the NNHPD.
- The NNHPD accepts all new applications through the designated NNHPD-initiated epost Connect™ conversation.
- The NNHPD will accept correspondence regarding Information Request Notices (IRNs) and Clarimails, requests for reconsideration, etc. through designated NNHPD-initiated epost Connect™ conversations.
- If a new application is submitted by epost Connect™ from a Delegated User, the Delegated User must have a Designated Party Authorization (DPA) form from the product licence holder. This is because the epost Connect™ account acts as the electronic signature for the ePLA (as verified through the Trading Partner enrolment process).

Benefits include:

- There is no cost to being a Trading Partner or corresponding through the epost Connect™ system (via NNHPD-initiated conversations).
- The application process is electronic and paperless, saving on paper and storage costs.
- Allows for more efficient processing (e.g. internal data entry) and sending of correspondence.
- Does not require a hard copy to be sent by regular mail.

4.2 SUBMITTING ON CD/DVD

Submitting an ePLA by CD/DVD is less efficient than epost Connect™; however, it still allows the NNHPD to maintain electronic records and, if using an ePLA, allows the application to proceed through a paperless process.

- When submitting an ePLA by CD/DVD, the senior official or delegated contact, with a DPA, must sign and print the attestation code on the top of the CD/DVD.
- Applicants must ensure that all documents are working and not password protected. Password protected or damaged files will not be processed and must be re-sent to the NNHPD.

4.3 SUBMITTING EPLA BY PAPER

Applicants can still benefit from the ePLA by printing the ePLA and sending it by mail or courier. When printed, the senior official or designated contact, with a DPA, must sign the finalized ePLA form.

Please note that all ePLAs, whether submitted electronically or by paper, must be finalized; only upon finalizing will the signature block appear when printed.

4.4 MAINTAINING ELECTRONIC FORMAT

When sending in a revised ePLA, the applicant must send the complete ePLA, not just the relevant pages, as this ensures that the NNHPD has the most up-to-date information, and helps facilitate update into our online systems.

Responses can be sent through the designated epost Connect™ conversation with a new, updated version of the ePLA at any time. Otherwise, respond in the way the initial application was submitted.

4.4.1 RESPONDING TO INFORMATION REQUEST NOTICES (IRNS) AND CLARIMAILS

When responding to IRNs and Clarimails, respond with the fully-revised ePLA. If initially submitted by CD, send in the response by CD to maintain electronic status. If the information is faxed or mailed in, the electronic status is compromised and there will be no benefit from the electronic tools or a paperless process. Additionally, during the response process, a complete ePLA may be submitted to replace a paper application form. If submitting a revised ePLA, please ensure that only what was requested is changed and the rest of the ePLA matches the previous paper version.

4.4.2 POST-LICENSING CHANGES ON AN EPLA

Any post-licence change (e.g. amendments and notifications) can be submitted using the ePLA. If the original application was submitted on paper, please ensure that the ePLA matches the originally-submitted paper PLA. The NNHPD requires a complete, finalised ePLA to be submitted for a post-licence change.

5. INQUIRIES AND ASSISTANCE

5.1 IMPORTANT CONTACTS

Trading Partner Management

- Address to be used exclusively with epost Connect™ (non-epost Connect™ messages will be returned)
- Requests for Trading Partner enrolment
- Request for modifications to an existing Trading Partner Profile

Submissions Management

- Address to be used exclusively with epost Connect™ (non-epost Connect™ messages will be returned)
- To submit new applications
- Correspondence relating to product or site licence applications, master files, etc.

Natural Health Product Ingredients Database Support via the NNHPD Ingredient Support email account

- Request additions or modifications of Ingredient Information to the NHPID via Issue Form
- Request additions or modifications of Controlled Vocabulary in the NHPID via Issue Form

Natural Health Products Online Solution via the NNHPD Online Solution Support email account

- Inquiries regarding Trading Partner Enrolment
- To report feedback or technical issues with NNHPD electronic tools and forms

Natural Health Product Licensing via the NNHPD Product Licensing email account

- Request contact information for Submission Coordinator
- Pre-submission meeting requests
- Product Licence correction requests and PLA withdrawal requests
- Company information updates
- To determine if your product meets the definition of a NHP
- Other inquiries regarding product licensing

Natural Health Products Site Licensing via the NNHPD Site Licensing email account

- Site Licence correction requests
- General inquiries regarding site licensing, Good Manufacturing Practices, and International Trade Certificates and Foreign Site Reference Number Application Process

Appendix A – Template for Proof of Signing Authority

(On company letterhead)

(Date)

To whom it may concern.

The following authorizes (Primary User), (Primary User Title) with (Trading Partner Legal Name) to act as the Primary User and as such has legal authority to sign for (Trading Partner Legal Name) in matters regarding the Natural Health Products Online Solution.

Respectfully,

(Corporate Officer name)
(Corporate Officer title)

Witnessed by:
(Witness name)